

Remarks/Arguments

Claims 1-41 and 57-59 have been withdrawn from consideration pursuant to the Examiner's restriction requirement and the applicant's election, with traverse, of claims 42-56. The applicant notes that the examiner has made the restriction final based on the allegation that although the three inventions relate to the same general concept, and that the general concept is not novel and is taught in the art by Blankenstein. As shown below, however, Blankenstein provides no such teaching.

Claims 42, 55, and 56 have each been amended to recite that the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone. Support for this amendment is found in the second full paragraph of page 45 (the second full paragraph of Example 4) wherein the specification states:

sudden changes in flow rate from zero to 200 $\mu\text{l/s}$ were used to displace captured particles from the magnetic cell tubing wall. Both 200 and 400 $\mu\text{l/s}$ flow rates were found to be effective for particle release, as determined by having no carryover enzyme-activity in subsequent blank runs. However, 200 $\mu\text{l/s}$ disperses the particles less than a 400 $\mu\text{l/s}$ pulse, and was preferred. Particle release was carried out in two directions.

Accordingly, no new matter is added by this amendment.

Claim 47 has been amended to provide the correct antecedent basis by changing "capture/dispersion region" to "capture zone" as recited in Claim 42. No new matter is added by this amendment.

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Claim 51 has been amended to provide the correct antecedent basis by changing “main port” to “primary port” as recited earlier in Claim 51. No new matter is added by this amendment.

Claims 52 and 53 have been amended to recite dependency to claim 51. No new matter is added by these amendments.

35 USC § 112

The examiner has rejected claims 47, 51, and 53 under 35 USC § 112. The examiner notes that claim 47 recites a “dispersion region” which lacks antecedent support. Claim 47 has been amended to provide the correct antecedent basis by changing “capture/dispersion region” to “capture zone” as recited in Claim 42. Accordingly, the applicant respectfully requests that the examiner withdraw this objection.

The examiner notes that claim 51 recites “the main port” which lacks antecedent support. Claim 51 has been amended to provide the correct antecedent basis by changing “main port” to “primary port” as recited earlier in Claim 51. Accordingly, the applicant respectfully requests that the examiner withdraw this objection.

The examiner notes that claim 53, which depends from claim 42, fails to recite antecedent support for the components “the multiport selection valve, the three-way valve and the pump.” Claims 52 and 53 have been amended to recite dependency to claim 51, which recites antecedent support for the components “the multiport selection valve, the three-way valve and the pump.” Accordingly, the applicant respectfully requests that the examiner withdraw this objection.

35 USC § 102(e)

The examiner has rejected claims 42-45, 52, and 54-56 as having been anticipated by Blankenstein (US 6,432,630). Claims 42, 55, and 56, and all remaining claims by virtue of dependency, have each been amended to recite that the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone. In contrast, while the fluid flow controller of Blankenstein is configured to operate at variable speeds, it is not configured to impose a pulse, as the system shown and described by Blankenstein does not trap particles in a capture zone. In fact, if the Blankenstein apparatus were operated in a fashion where particles were trapped in a capture zone, such would defeat the purpose of the Blankenstein apparatus. Blankenstein operates by deflecting particles out of a laminar flow within a flow channel into a sort outlet. Blankenstein does so by carefully controlling the fluid flow of two guiding buffers through the flow channel and through the sort outlet, and applying a field to the particles of interest such that they are directed through the sort outlet, while other particles flow through a waste outlet. Thus, if the field of Blankenstein were sufficiently large to capture particles in a capture zone, the fundamental operating principle through which Blankenstein separates particles of interest would be violated, and Blankenstein would cease to function effectively.

Blankenstein is only able to effect separations by maintaining a careful balance between the flow rates of the guiding buffers and the field such that the particles of interest are deflected precisely the right amount to cause separation. Were the particles trapped in a capture zone, as in the case of the present invention, this careful balance would be upset, and Blankenstein would no longer effectively separate particles. Similarly, the pulse of the present invention would also violate the fundamental operating principle through which Blankenstein separates particles of interest and cause Blankenstein to cease to function effectively. Any pulse in the fluid flows in the Blankenstein system would overwhelm the delicate balance whereby the particles of interest are directed to the sort

outlet while particles of interest are directed to the sort outlet. Blankenstein makes this point explicitly at column 25-33 where Blankenstein states:

Thereby, inertial effects, which causes turbulence and secondary flows are negligible, viscous effects dominate the dynamics, and mixing is caused only by diffusion. Flow of the sample, which is the fluid containing particles and guiding buffers can be laminated in guided layers through the channel and displacement of particles in the channel is only caused by the external force applied.

Since the pulse of the present invention inherently introduces turbulence into the fluid flow, Blankenstein teaches directly away from configurations claimed in the present invention. Where the effectiveness of particle separation in the Blankenstein system is adversely effected by pulses in the fluid flow and the resultant turbulence, the present invention depends on such pulses to separate particles. Accordingly, the invention as now claimed, where it is specified that “the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone” is completely distinguished from Blankenstein.

A proper rejection under 35 U.S.C. 102(e) must contain each and every limitation of the claim, (“[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration” W.L. Gore & Assocs. V. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Accordingly, Blankenstein cannot possibly form the basis for a prima facie rejection under 35 U.S.C. 102(e) as Blankenstein not only fails to teach or suggest a “fluid flow controller effective to impose a pulse,” Blankenstein in fact teaches directly away from such a fluid flow controller. Accordingly, the applicant respectfully requests that the examiner withdraw this rejection of claims 42-45, 52, and 54-56 as having been anticipated by Blankenstein (US 6,432,630).

The examiner has rejected claim 56 as having been anticipated by Davidson (US 6,482,328). Claim 56 has been amended to recite that the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone. In contrast, the fluid flow controller of Davidson is not configured to impose a pulse, as the system shown and described by Davidson removes particles trapped in a capture zone by effectively eliminating the field that creates the capture zone.

The present invention is thus distinguished from Davidson because the present invention is specifically configured to remove particles trapped in a capture zone without removing the field that creates the capture zone. The applicant makes this distinction explicit at the third paragraph of page 14 wherein the applicant states:

By controlling fluid flow rates through a fixed magnetic field in capture zone 40, as described above, the present invention provides systems that differ from prior art separation/resuspension by eliminating the need for removal of the magnetic field such as by physical movement of a permanent magnet away from the flow path or, where an electromagnet is used, by turning off the electromagnet or effecting field fluctuations or reversals.

Davidson is exactly such a prior art method. At column 2, lines 22-30, Davidson states:

According to further features in the described preferred embodiments, the magnetically-stained target particles in the sample mixture, which are separated and retained in the buffer liquid within the tube at the magnetizing station, are subsequently removed from the tube *by terminating ... the application of the magnetic field across the tube*, while the buffer liquid is fed through the tube to flush out the magnetically-stained target particles with the buffer liquid. (italics added).

Accordingly, Davidson operates in exactly the way that produces the problems the present invention was designed to overcome. Davidson removes trapped particles by turning off the field. The present invention removes trapped particles by “impos[ing] a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone.” In contrast, the fluid flow controller of Davidson is configured to operate at a constant speed. At column 6, lines 25-36, Davidson makes this constant flow explicit:

Thus, the system illustrated in FIG. 2 includes a microprocessor controller, generally designated 20, for controlling the overall operation of the system. The inputs to controller 20 include a flow selector 21 for presetting the flow rate of feed of the buffer liquid from the buffer container 11; an air bubble sensor 22 for sensing the presence of air bubbles in the buffer feed tube 12; and an air bubble sensor 23 for sensing the presence of air bubbles in the sample feed tube 17. These sensors protect the integrity of the constant fluid level by shutting down fluid flow (sensor 22 will close valve 27, and sensor 23 will close valve 28) if an air bubble is detected. Controller 20 also includes an input from a flow rate sensor 29 for sensing the flow into container 14.

As such, not only is the controller shown and described by Davidson not configured to impose a pulse (as is required by claim 56), the Davidson disclosure explicitly teaches away from such a pulse. Accordingly, the invention as now claimed, where it is specified that “the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone” is completely distinguished from Davidson.

A proper rejection under 35 U.S.C. 102(e) must contain each and every limitation of the claim, (“[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration” *W.L. Gore & Assocs. V. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983)). Accordingly, Davidson cannot possibly

form the basis for a prima facie rejection under 35 U.S.C. 102(e) as Davidson not only fails to teach or suggest a “fluid flow controller effective to impose a pulse,” Davidson in fact teaches directly away from such a fluid flow controller. Accordingly, the applicant respectfully requests that the examiner withdraw this rejection of claim 56 as having been anticipated by Davidson (US 6,482,328).

The examiner has rejected claims 42-45, 47-54 and 56 as having been anticipated by Chandler et al. (International Journal of Food Microbiology, vol. 70, No. 1-2, 22 October 2001 (22.10.2001), pp. 43-154). The applicant notes that the instant application was filed in the United States Patent and Trademark Office on August 31, 2001. The applicant was then provided with an official filing receipt, showing that the United States Patent and Trademark Office had properly designated the filing date of the present application as August 31, 2001. Indeed, the instant office action recites the filing date of the present application as August 31, 2001.

As shown by the examiner, the publication date of the Chandler et al. reference is October 22, 2001. October 22, 2001 came after August 31, 2001. Accordingly, the Chandler et al. reference is not properly considered as prior art, as it was not published until after the filing date of the instant application. The applicant therefore respectfully requests that the examiner withdraw this rejection of claims 42-45, 47-54 and 56 as having been anticipated by Chandler et al. (International Journal of Food Microbiology, vol. 70, No. 1-2, 22 October 2001 (22.10.2001), pp. 43-154).

35 USC § 103(a)

The examiner has rejected claim 49 as unpatentable over Blankenstein (US 6,432,630). The examiner notes that Blankenstein fails to disclose a controller effective to provide a flow rate in the fluid flow path ranging up to about 2500 mm/s in either direction, but argues that it would have been obvious to one of ordinary skill in the art to use such a controller through routine experimentation. Even if the examiner is correct, claim 49 has

been amended by virtue of dependency to recite that the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone. As discussed above, Blankenstein teaches directly away from the controller configuration as it is claimed in claim 49 of the present invention.

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Where, as in the instant case, the reference teaches directly away from the invention, the examiner cannot possibly set forth a prima facie case of obviousness, because the reference expressly suggests that the claimed invention will not be effective in achieving the ends sought. Accordingly, no convincing line of reasoning is possible that would show that the reference would lead a skilled artisan to conclude to the claimed invention. Therefore, the applicant respectfully requests that the examiner withdraw this rejection of claim 49 as being unpatentable over Blankenstein (US 6,432,630).

The examiner has rejected claims 51 as unpatentable over Blankenstein (US 6,432,630) in view of Wade (US 5,695,720). The examiner notes that Blankenstein fails to disclose a multiport selection valve including a primary port and a plurality of secondary ports, wherein a first secondary port is fluidly connected to the inlet of the fluid flow path; a holding coil having a proximal end and a distal end; wherein the distal end is fluidly connected to the main port of the selection valve; a three-way valve having a first port fluidly connected to the proximal end of the holding coil; a second port fluidly connected to a variable speed reversible pump; and a third port fluidly connected to a source of a wash composition, but argues that Wade teaches these elements, and that it would have been obvious to one of ordinary skill in the art to combine the teachings of Blankenstein with the teachings of Wade.

However, even if the examiner is correct, claim 51 has been amended by virtue of dependency to recite that the fluid flow controller is effective to impose a pulse in said flow in said first or second direction sufficient to dislodge magnetic particles trapped in said capture zone. As discussed above, Blankenstein teaches directly away from this controller configuration as it is now claimed in claim 51 of the present invention. Wade does nothing to remedy these deficiencies, as Wade does not even remotely consider the use of magnetic particles, much less a capture zone or a fluid flow controller effective to impose a pulse sufficient to dislodge magnetic particles trapped in the capture zone.

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Where, as in the instant case, the Blankenstein reference teaches directly away from the invention, the examiner can only set forth a prima facie case of obviousness if the examiner can establish that the Wade reference remedies the deficiencies of Blankenstein, because the Blankenstein reference expressly suggests that the claimed invention will not be effective in achieving the ends sought. However, as noted above, Wade cannot possibly provide this remedy, as Wade does not even consider the use of magnetic particles, a capture zone, or a fluid flow controller effective to impose a pulse sufficient to dislodge magnetic particles trapped in the capture zone.

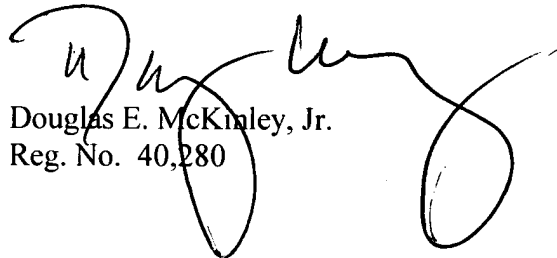
Accordingly, no convincing line of reasoning that would show that the Blankenstein and Wade references should even be combined, much less that the combination would lead a skilled artisan to conclude to the invention claimed in claim 51. The applicant therefore respectfully requests that the examiner withdraw this rejection of claim 51 as being unpatentable over Blankenstein (US 6,432,630) in view of Wade (US 5,695,720).

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Conclusion

Applicant has made an earnest attempt to place the above referenced application in condition for allowance and action toward that end is respectfully requested. If the not allowed, the applicant respectfully requests that the amendments to the claims and specification set forth herein nevertheless be entered into the record. Should the Examiner have any further observations or comments, she is invited to contact the undersigned for resolution.

Respectfully submitted,



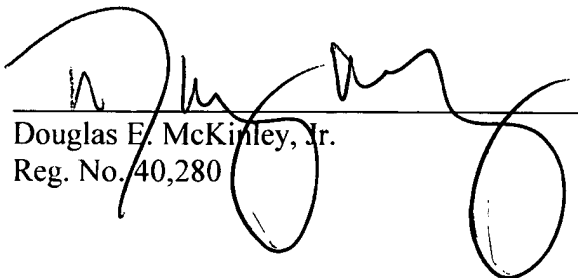
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The undersigned hereby certifies that the forgoing Amendment dated February 14, 2006 in Response to Office action of October 14, 2005, together with USPTO Form PTO/SB/22 and a return postcard are being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to

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on the date set forth below.



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February 14, 2006
Date